

Notice of Allowability

Application No.

09/486,882

Examiner

Christopher M. Gross

Applicant(s)

MCGREGOR, DUNCAN

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/25/2007.
2. ☒ The allowed claim(s) is/are 1,3-7,9 and 24-26.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

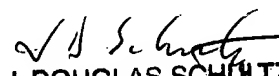
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 7/13/2007.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


J. DOUGLAS SCHULTZ, PH.D.
SUPERVISORY PATENT EXAMINER

DETAILED ACTION

Status of the Application

Receipt is acknowledged of a responsive amendment, which was dated on May 25, 2007.

Status of the Claims

Claims 1,3-7,9,24-26 were pending. Applicants amended claims 1, 7, 24 and 25. Therefore, claims 1,3-7,9,24-26 are currently pending and examined on the merits.

Please note that all previous species elections are hereby withdrawn in view of the fact that the art search was extended to all species and no prior art was found that anticipates or renders obvious the instant claims in accordance with MPEP § 803.02. In view of the above noted withdrawal of the restriction requirement as to the linked species, applicant(s) are advised that if any claim(s) depending from or including all the limitations of the allowable generic linking claim(s) be presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

EXAMINER'S AMENDMENT

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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Eric Sumner on 7/13/2007 (see attached interview summary)

The application has been amended as follows:

Claims

1. (Currently Amended) A An isolated synthetic construct which is a peptide display carrier package (PDCP), said construct comprising a complex of a recombinant single-stranded polynucleotide and a chimeric protein, wherein
 - i) the chimeric protein has
 - a) a nucleotide binding portion which comprises a binding domain of an estrogen receptor; and
 - b) a target peptide portion displayed externally on the package,
 - ii) said recombinant single-stranded polynucleotide comprises
 - a) a chimeric protein-encoding portion which encodes the chimeric protein of the complex; and
 - b) a nucleotide sequence motif which is specifically bound by said nucleotide binding portion of the chimeric protein,and wherein the nucleotide binding portion of the chimeric protein is bound to the nucleotide sequence motif of the recombinant single-stranded polynucleotide, and wherein the chimeric protein-encoding portion of the recombinant single-stranded polynucleotide is not bound by the nucleotide binding portion of the chimeric protein, and wherein the chimeric protein-encoding portion of the recombinant polynucleotide is protected from degradation by a binding moiety which is a viral protein and which is bound non-specifically to the single-stranded

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polynucleotide irrespective of nucleotide sequence, and wherein said construct is produced in a host cell transformed with said recombinant single-stranded polynucleotide and extruded therefrom without lysis of the host cell.

2. (Cancelled).
3. ~~(Original)~~-(Previously Amended) A construct as claimed in Claim 1, wherein the binding moiety is a viral coat protein.
4. ~~(Original)~~-(Previously Amended) A construct as claimed in Claim 1, wherein said target peptide portion is displayed externally on the package.
5. ~~(Original)~~-(Currently Amended) A construct as claimed in Claim 1 wherein said recombinant single-stranded polynucleotide includes a linker sequence between the nucleotide sequence encoding the nucleotide binding portion and the nucleotide sequence encoding the target peptide portion.
6. ~~(Original)~~-(Currently Amended) A construct as claimed in Claim 1 wherein said recombinant single-stranded polynucleotide has two or more nucleotide sequence motifs wherein each of the nucleotide sequence motifs is bound by the nucleotide binding portion of the chimeric protein.
7. (Currently Amended) A construct as claimed in Claim 1 wherein said nucleotide-binding portion is a DNA binding domain of an estrogen receptor.
8. (Cancelled).
9. (Original) A construct as claimed in Claim 1 wherein said target peptide portion is located at the N and/or C terminal of the chimeric protein.

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10. (Cancelled).
11. (Cancelled).
12. (Cancelled).
13. (Cancelled).
14. (Cancelled).
15. (Cancelled).
16. (Cancelled).
17. (Cancelled).
18. (Cancelled).
19. (Cancelled).
20. (Cancelled).
21. (Cancelled).
22. (Cancelled).
23. (Cancelled).
24. (Currently Amended) A An isolated synthetic construct for use as peptide display carrier package (PDCP), said construct comprising a recombinant

polynucleotide-chimeric protein complex wherein the chimeric protein has a nucleotide binding portion which comprises a binding domain of an estrogen receptor and a target peptide portion, wherein said recombinant polynucleotide is a single-stranded polynucleotide and comprises a ~~chimeric protein-encoding portion~~ chimeric protein-encoding portion and a nucleotide sequence motif which is specifically bound by said nucleotide binding portion, and wherein the chimeric protein-encoding portion of the recombinant single-stranded polynucleotide not bound by the chimeric protein nucleotide binding portion is protected from degradation by a binding moiety which is a viral protein and which is bound to the recombinant single-stranded polynucleotide irrespective of the nucleotide sequence, wherein said binding moiety is a viral coat protein, wherein said target peptide portion is displayed externally on the package, wherein said recombinant single-stranded polynucleotide includes a linker sequence between the nucleotide sequence encoding the nucleotide binding portion and the nucleotide sequence encoding the target peptide portion, wherein said recombinant single-stranded polynucleotide has two or more nucleotide sequence motifs at least one is bound by the nucleotide binding portion of the chimeric protein, wherein said nucleotide binding portion is a DNA binding domain of an estrogen receptor.

25. (Currently Amended) A An isolated synthetic construct for use as peptide display carrier package (PDCP), said construct comprising a recombinant single-stranded polynucleotide-chimeric protein complex wherein the chimeric protein has a nucleotide binding portion which comprises a binding domain of an estrogen receptor and a target peptide portion, displayed externally on the package wherein said recombinant single-stranded polynucleotide comprises a ~~chimeric protein-encoding portion~~ chimeric protein-encoding portion and a nucleotide sequence motif which is specifically bound by said nucleotide binding portion, and wherein the chimeric protein-encoding portion of the recombinant single-stranded polynucleotide not bound by the chimeric protein nucleotide binding portion is protected from degradation by a binding moiety which is a viral

protein and which is bound to the polynucleotide irrespective of the nucleotide sequence, wherein said recombinant single-stranded polynucleotide is bound to said chimeric protein ~~as single-stranded DNA~~, wherein said target peptide portion is located at the N and/or C terminal of the chimeric protein and said construct is produced in a host cell transformed with said recombinant single-stranded polynucleotide and extruded therefrom without lysis of the host cell.

26. (Previously Presented) A construct as claimed in Claim 1 wherein the binding moiety is a bacteriophage coat protein.

Specification

Table 1, below inserting sequence identifiers as indicated will substituted for table 1 shown on pp 66-68 of the specification.

Table 1 (i) Oligonucleotide primers used for human scFv library construction

cDNA synthesis primers

IgMCDNAFOR	TGGAAGAGGCACGTTCTTTTCTTT SEQ ID NO: 37
IgDCDNAFOR	CTCCTTCTTACTCTTGCTGGCGGT SEQ ID NO: 38
Ig κ CDNAFOR	AGACTCTCCCCTGTTGAAGCTCTT SEQ ID NO: 39
Ig λ CDNAFOR	TGAAGATTCTGTAGGGGCCACTGTCTT SEQ ID NO: 40

JHFOR primers

JH1-2FOR	TGAACCGCCTCCACCTGAGGAGACGGTGACCAGGGTGCC SEQ ID NO: 41
JH3FOR	TGAACCGCCTCCACCTGAAGAGACGGTGACCATTGTCCC SEQ ID

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JH4-5FOR NO: 42
TGAACCGCCTCCACCTGAGGAGACGGTGACCAGGGTTCC SEQ ID
NO: 43
JH6FOR TGAACCGCCTCCACCTGAGGAGACGGTGACCGTGGTCCC SEQ ID
NO: 44

VH family BAK primers

VH1BAK TTTTGGCCCAGCCGGCCATGGCCCAGGTGCAGCTGGTGCAGTCTGG SEQ
ID NO: 45
VH2BAK TTTTGGCCCAGCCGGCCATGGCCCAGGTCAACTTAAGGGAGTCTGG SEQ
ID NO: 46
VH3BAK TTTTGGCCCAGCCGGCCATGGCCGAGGTGCAGCTGGTGGAGTCTGG SEQ
ID NO: 47
VH4BAK TTTTGGCCCAGCCGGCCATGGCCCAGGTGCAGCTGCAGGAGTCGGG SEQ
ID NO: 48
VH5BAK TTTTGGCCCAGCCGGCCATGGCCGAGGTGCAGCTGTTGCAGTCTGC SEQ
ID NO: 49
VH6BAK TTTTGGCCCAGCCGGCCATGGCCCAGGTACAGCTGCAGCAGTCAGG SEQ
ID NO: 50

Light chain FOR primers

SCFVKFOR TTATTCGCGGCCGCCTAAACAGAGGCAGTTCAGATTTC SEQ ID NO:
51
SCFVλFOR GTCACCTGCGGCCGCCTACAGTGTGGCCTTGTTGGCTTG SEQ ID
NO: 52

VK family BAK primers

VK1BAK TCTGGCGGTGGCGGATCGGACATCCAGATGACCCAGTCTCC SEQ ID
NO: 53

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VK2BAK TCTGGCGGTGGCGGATCGGATGTTGTGATGACTCAGTCTCC SEQ ID
NO: 54

VK3BAK TCTGGCGGTGGCGGATCGGAAATTGTGTTGACGCAGTCTCC SEQ ID
NO: 55

VK4BAK TCTGGCGGTGGCGGATCGGACATCGTGATGACCCAGTCTCC SEQ ID
NO: 56

VK5BAK TCTGGCGGTGGCGGATCGGAAACGACACTCACGCAGTCTCC SEQ ID
NO: 57

VK6BAK TCTGGCGGTGGCGGATCGGAAATTGTGCTGACTCAGTCTCC SEQ ID
NO: 58

JK FOR primers

JK1FOR TTCTCGTGCGGCCGCCTAACGTTTGATTTCACCTTGGTCCC SEQ ID NO:
59

JK2FOR TTCTCGTGCGGCCGCCTAACGTTTGATCTCCAGCTTGGTCCC SEQ ID NO:
60

JK3FOR TTCTCGTGCGGCCGCCTAACGTTTGATATCCACTTTGGTCCC SEQ ID NO: 61

JK4FOR TTCTCGTGCGGCCGCCTAACGTTTGATCTCCACCTTGGTCCC SEQ ID NO:
62

JK5FOR TTCTCGTGCGGCCGCCTAACGTTTAATCTCCAGTCGTGTCCC SEQ ID NO:
63

V λ family BAK primers

V λ 1BAK TCTGGCGGTGGCGGATCGCAGTCTGTGTTGACGCAGCCGCC SEQ ID
NO: 64

V λ 2BAK TCTGGCGGTGGCGGATCGCAGTCTGCCCTGACTCAGCCTGC SEQ ID
NO: 65

Table 1 (ii) Oligonucleotide primers used for human scFv library construction

V λ 3aBAK TCTGGCGGTGGCGGATCGTCCTATGTGCTGACTCAGCCACC SEQ ID
NO: 66

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Vλ3bBAK TCTGGCGGTGGCGGATCGTCTTCTGAGCTGACTCAGGACCC SEQ ID
NO: 67

Vλ4BAK TCTGGCGGTGGCGGATCGCACGTTATACTGACTCAACCGCC SEQ ID
NO: 68

Vλ5BAK TCTGGCGGTGGCGGATCGCAGGCTGTGCTCACTCAGCCGTC SEQ ID
NO: 69

Vλ6BAK TCTGGCGGTGGCGGATCGAATTTTATGCTGACTCAGCCCCA SEQ ID
NO: 70

Jλ primers

Jλ1FOR TTCTCGTGCGGCCGCCTAACCTAGGACGGTGACCTTGGTCCC SEQ ID
NO: 71

Jλ2-3FOR TTCTCGTGCGGCCGCCTAACCTAGGACGGTCAGCTTGGTCCC SEQ ID
NO: 72

Jλ4-5FOR TTCTCGTGCGGCCGCCTAACCTAAACGGTGAGCTGGGTCCC SEQ ID
NO: 73

Linker primers

LINKAMP3 CGATCCGCCACCGCCAGA SEQ ID NO: 74

LINKAMP5 GTCTCCTCAGGTGGAGGC SEQ ID NO: 75

LINKAMP3T CGATCCGCCACCGCCAGAGCCACCTCCGCCTGAACCGCCTCCACCTGA
GGAGAC SEQ ID NO: 76

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

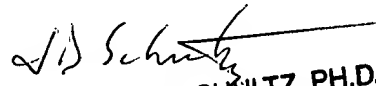
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

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J. DOUGLAS SCHULTZ, PH.D.
SUPERVISORY ~~PATENT~~ EXAMINER